

Berndl et al.

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REMARKS

Claims 10-21 are currently pending. Claims 10 and 19 are amended. Claim 21 is new.

Rejections Under USC § 103 (a)**Claims 10-20 Rejected**

To establish *prima facie* obviousness, the examiner must show in the prior art some suggestion or motivation to make the claimed invention, a reasonable expectation for success in doing so, and a teaching or suggestion of each claim element (*see, e.g., In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ 2d 1941 (Fed. Cir. 1992); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)).

Claims 10-14, 17, 19 and 20 are rejected under 35 USC 103 (a) as allegedly being unpatentable in light of US 4,127,422. US 4,127,422 refers to dry pigment compositions comprising 55 to 80% of a pigment and 45 to 20% of a nonionic material, which nonionic material is formed of a nonionic dispersing agent and a polymer such as polyvinylpyrrolidone. A homogeneous mixture of the pigment and the nonionic material is formed, which mixture is dried. Mixing can be performed by mixing the components in one stage or by mixing the pigment in the presence of water with the nonionic dispersing agent followed by addition of the polymer and drying.

The examiner has argued that US 4,127,422 teaches the preparation of dry excipients. US 4,127,422 discloses a dry pigment composition functioning as the "active ingredient", i.e. the ingredient that is to be formulated with the nonionic components so that a stable aqueous dispersion of the pigment can be formed (see column 1, lines 10-17). Thus, according to US 4,127,422, no dry excipients are formed, only formulations of the "active" pigment and excipients. The instant invention is directed to a process for preparing excipient compositions that do not contain an active ingredient. Liquid or semi-solid surface-active substances, which are otherwise difficult to handle, are mixed with a specific polymer and then formed into a dry composition consisting essentially of the surface-active substance and the polymer. Therefore, US 4,127,422 neither teaches nor suggests the instant invention.

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Applicants urge that the language "consisting essentially of" used in Claim 10 does exclude the presence of US 4,127,422's pigment in the excipient. Nonetheless, the Examiner is directed to new Claim 21 wherein pigments are excluded from the instant invention.

Claim 19, as a dependent claim, should not be read as broadening the scope of Claim 10. In any event, Applicants have amended Claim 19 to clarify that other ingredients may be added to the excipient produced by the process of Claim 10 after preparation of the free flowing powder.

Claims 15 and 16 are rejected under 35 USC § 103(a) as allegedly being unpatentable over the combined disclosures of US 4,127,422, US 6,011,096 and US 5,993,805. The Examiner believes one of ordinary skill in the art would combine the surfactants of US 6,011,096 into the process of US 4,127,422, under its suggestion to improve the purity and stability. The Examiner believes a skilled artisan would have been motivated to combine the surfactant of US 5,993,805 into the process of US 4,127,422 under its suggestions to improve the stability of the formulation. The Examiner believes it would have been obvious to one of ordinary skill in the art to combine the teachings and suggestions as such with an expected result of a spray dried excipient with improved stability and purity.

The Applicants respectfully disagree. The combined teachings of US 6,011,096 and US 5,993,805 do not add to the teaching of US 4,127,422 that would lead to the instant invention.

US 6,011,096 teaches a process for polymerization of N-vinyl pyridine polymers in the presence of a suspension agent, (e.g. polyvinylpyrrolidone) and optionally, also in the presence of a water-soluble emulsifier to give an aqueous polyvinylpyridine suspension. US 6,011,096 does not teach or suggest making an excipient which is a mixture of a polymer and a liquid or surface active agent. US 6,011,096 discloses solely a polymerization process of a polymer (polyvinylpyridine) not within the claimed range of the instant invention, wherein the surface active agent is present during polymerization but subsequently removed with the aqueous polymerization medium.

US 5,993,805 teaches the formation of spray-dried hollow microcapsules comprising a pharmaceutical active ingredient together with e.g. polyvinylpyrrolidone and a surfactant.

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Neither of the references alone or in combination teach nor suggest the claimed process for making dry excipient consisting of a polymer and the surface active agent but not containing an active in order to improve handling of the surface active substance.

Claim 18 is rejected under 35 USC 103(a) as being unpatentable over US 4,127,422 and US 5,840,759. The Examiner believes that one of ordinary skill in the art would have been motivated to include the PVP composition of US 5,840,759 into the process of US 4,127,422 to improve the flow of the excipient and reduce agglomeration. Therefore, the Examiner believes it would have been obvious to combine these teachings with an expected result of spray-dried excipient with improved flow and agglomeration properties.

The Applicants respectfully disagree. The Examiner is directed to the compositions disclosed by US 5,840,759. The disclosed compositions comprise the soluble PVP in amounts of up to 15 % b.w. The Examiner is also directed to the cited reference's main constituent, powdered cellulose, comprising at least 75 % b.w. PVP, according to US 5,840,759, is used to increase plasticity of cellulose powders. PVP is added during granulation in order to increase plasticity because of the poor flow properties of this cellulose powder. Thus, one of ordinary skill in the art would not be motivated to consider including PVP when trying to find an excipient comprising liquid or semisolid active substances (i.e. substances that are already too "plastic" for convenient handling) because the inclusion of PVP increases a substances plasticity of an already too plastic substance.

For the reasons expressed above, it is urged that the prior art references cited by the examiner either singly or in combination fail to anticipate or suggest the present invention as defined by the amended claims. Accordingly, a *prima facie* case of obviousness has not been established by the examiner and the rejection under 35 USC § 103 should be withdrawn.

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